

AMENDED IN SENATE AUGUST 23, 2006

AMENDED IN SENATE AUGUST 7, 2006

AMENDED IN SENATE JUNE 19, 2006

AMENDED IN ASSEMBLY MAY 8, 2006

AMENDED IN ASSEMBLY APRIL 4, 2006

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 2156

Introduced by Assembly Member Niello

February 21, 2006

An act to amend Section 1209.1 of, and to add Sections 1209.5 and 1269.3 to, the Business and Professions Code, relating to clinical laboratories.

LEGISLATIVE COUNSEL'S DIGEST

AB 2156, as amended, Niello. Clinical laboratories.

Existing law provides for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services. Existing law makes a violation of these provisions a crime.

Existing law defines a "histocompatibility laboratory director" as any person who is (1) a duly licensed physician, (2) a bioanalyst, or (3) a person who has earned a doctoral degree in a biological science and has completed, as specified, 4 years of experience in immunology; 2 of which have been in histocompatibility testing.

This bill would require an applicant for licensure as a histocompatibility laboratory director, on and after January 1, 2007, to successfully complete a written exam administered by the American

~~Board of Histocompatibility and Immunogenetics and an oral exam administered by the department.~~

Existing law defines a “laboratory director” as any person that is a duly licensed physician and surgeon or is licensed to direct a clinical laboratory and who meets specified qualifications. Existing law makes laboratory directors responsible for the overall operation and administration of clinical laboratories which includes, among other things, the reporting of results.

This bill would require a laboratory director or a licensed authorized designee appointed by the laboratory director to establish, validate, and document explicit criteria by which clinical laboratory tests or examination results are autoverified, as defined. The bill would also require a laboratory director or an authorized designee, annually, to revalidate the criteria. The bill would require specified licensed persons to be physically present onsite in the clinical laboratory *and to have documented competency in all tests being autoverified*, and it would make these specified licensed persons responsible for the accuracy and reliability of the results when they are autoverified and reported.

Existing law defines a “histocompatibility laboratory director” as any person who is (1) a duly licensed physician, (2) a bioanalyst, or (3) a person who has earned a doctoral degree in a biological science and has completed, as specified, 4 years of experience in immunology, 2 of which have been in histocompatibility testing. Existing law also defines and sets forth qualifications for a “clinical laboratory bioanalyst.”

This bill would add to the requirements of a histocompatibility laboratory director (1) a requirement that a physician and surgeon be qualified as a laboratory director, (2) a requirement that a bioanalyst be qualified as a clinical laboratory bioanalyst and as a laboratory director, and (3) a requirement that, on and after January 1, 2007, a person who has earned a doctoral degree in biological science successfully complete a written exam administered by the American Board of Histocompatibility and Immunogenetics and an oral exam administered by the department.

Under existing law, unlicensed laboratory personnel are authorized to perform specified activities, in a licensed clinical laboratory, under the direct and constant supervision of a physician and surgeon or another licensed person if certain criteria are met. Existing law authorizes these unlicensed laboratory personnel to perform specimen

labeling, handling, preservation or fixation, processing or preparation, transportation, and storing.

This bill would authorize a certified pathologists' assistant, within the specialty of pathology, demonstrating specified competency, to perform specified activities under the supervision and control of a pathologist. The bill would authorize a pathologists' assistant, a histologic technician, and a histotechnologist to prepare human surgical specimens for gross description and dissection under the direct supervision, as defined, of a qualified pathologist, if he or she meets specified requirements. The bill would authorize the department, on and after January 1, 2011, to adopt regulations establishing additional qualification requirements to perform the duties specified in these provisions.

Because the bill would revise requirements pertaining to clinical laboratories and their personnel, a violation of which would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. Section 1209.1 of the Business and Professions
2 Code is amended to read:
3 1209.1. (a) As used in this chapter, "histocompatibility
4 laboratory director" means *a physician and surgeon licensed to*
5 *practice medicine pursuant to Chapter 5 (commencing with*
6 *Section 2000) who is qualified pursuant to Section 1209, a*
7 *bioanalyst licensed pursuant to Section 1260 who is qualified*
8 *pursuant to Sections 1203 and 1209, or a person who has earned*
9 *a doctoral degree in a biological science, who has completed,*
10 *subsequent to graduation, four years of experience in*
11 *immunology, two of which have been in histocompatibility*
12 *testing, and who meets one of the following requirements:*
13 ~~(1) Is a licensed physician and surgeon.~~

1 ~~(2) Is a bioanalyst.~~

2 ~~(3) Has earned a doctoral degree in a biological science.~~
3 ~~testing.~~

4 (b) On and after January 1, 2007, in order to be eligible for
5 licensure as a histocompatibility laboratory director, an applicant
6 *who is not a duly licensed physician and surgeon or a duly*
7 *licensed bioanalyst* shall provide evidence of satisfactory
8 performance on a written examination in histocompatibility
9 administered by the American Board of Histocompatibility and
10 Immunogenetics, and have demonstrated satisfactory
11 performance on an oral examination administered by the
12 department regarding this chapter and Part 493 (commencing
13 with Section 493.1) of Subchapter G of Chapter IV of Title 42 of
14 the Code of Federal Regulations.

15 (c) A person licensed under Section 1260.1 as a
16 histocompatibility laboratory director and qualified under CLIA
17 may perform clinical laboratory tests or examinations classified
18 as of high complexity under CLIA and the duties and
19 responsibilities of a laboratory director, technical consultant,
20 clinical consultant, technical supervisor, and general supervisor,
21 as specified under CLIA, in the specialty of histocompatibility,
22 immunology, or other specialty or subspecialty specified by
23 regulation adopted by the department. A person licensed as a
24 “histocompatibility laboratory director” may perform any clinical
25 laboratory test or examination classified as waived or of
26 moderate complexity under CLIA.

27 SEC. 2. Section 1209.5 is added to the Business and
28 Professions Code, to read:

29 1209.5. (a) “Autoverification” means the use of a computer
30 algorithm in conjunction with automated clinical laboratory
31 instrumentation to review and verify the results of a clinical
32 laboratory test or examination for accuracy and reliability.

33 (b) The laboratory director or authorized designee shall
34 establish, validate, and document explicit criteria by which the
35 clinical laboratory test or examination results are autoverified.

36 (c) The laboratory director or authorized designee shall
37 annually revalidate the explicit criteria by which the clinical
38 laboratory test or examination results are autoverified. The
39 laboratory director shall approve and annually reapprove the
40 computer algorithm.

(d) An authorized designee shall be appointed by the laboratory director for the purposes of this section. The authorized designee shall be licensed to engage in clinical laboratory practice pursuant to this chapter and shall be qualified as a clinical consultant, technical supervisor, general supervisor, or technical consultant pursuant to regulations adopted by the department.

(e) A person licensed to perform the applicable type and complexity of testing pursuant to Section 1206.5 shall be physically present onsite in the clinical laboratory *and shall have documented competency pursuant to Section 1209 in all tests being autoverified*, and shall be responsible for the accuracy and reliability of the results of the clinical laboratory test or examination when the results are autoverified and reported.

SEC. 3. Section 1269.3 is added to the Business and Professions Code, to read:

1269.3. (a) Notwithstanding Sections 1206.5 and 1269, within the specialty of pathology, a person certified as a pathologists' assistant by the American Association of Pathologists' Assistants, the Board of Registry of the American Society for Clinical Pathology, or another national accrediting agency approved by the department, who demonstrates competency to perform all job duties and responsibilities before an assignment to those duties and responsibilities, at the completion of six months of performing those duties and responsibilities, and annually thereafter, may perform the following activities under the supervision and control of a pathologist:

(1) Prepare human surgical specimens for gross description and dissection, including, but not limited to, description of gross features and selection of tissues for histological examination.

(2) Prepare and perform human postmortem examinations, including, but not limited to, selection of tissues and fluids for further examination.

(3) Gather other information necessary for an autopsy report.

(4) Prepare a body for release.

(b) Notwithstanding Section 1206.5 or subdivisions (b), (c), and (d) of Section 1269, the following persons may prepare human surgical specimens for gross description and dissection under the direct supervision of a qualified pathologist, including,

1 description of gross features and selection of tissues for
2 histological examination, if they meet the requirements specified
3 in subdivision (a) of Section 1269 and the minimum education
4 and training requirements for high complexity testing personnel
5 under the CLIA:

6 (1) A pathologists' assistant who does not meet the
7 certification requirements of subdivision (a).

8 (2) A histologic technician.

9 (3) A histotechnologist.

10 (c) For the purposes of subdivision (b), direct supervision
11 means that a qualified pathologist shall be physically present
12 onsite in the vicinity of the clinical laboratory where the specialty
13 of pathology is performed and shall be available for consultation
14 and direction during the time the personnel specified in
15 subdivision (b) are engaged in the processing of specimens that
16 involve dissection. For tissue processing that does not involve
17 dissection, a qualified pathologist may be available by telephone
18 or other electronic means.

19 (d) A histologic technician or histotechnologist who meets the
20 requirements specified in subdivision (a) of Section 1269, may
21 accession specimens, perform maintenance of equipment, stain,
22 cover slip, label slides, and process tissues by embedding in
23 paraffin or performing microtomy.

24 (e) On and after January 1, 2011, the department may adopt
25 regulations establishing additional qualification requirements to
26 perform the duties described in this section.

27 SEC. 4. No reimbursement is required by this act pursuant to
28 Section 6 of Article XIII B of the California Constitution because
29 the only costs that may be incurred by a local agency or school
30 district will be incurred because this act creates a new crime or
31 infraction, eliminates a crime or infraction, or changes the
32 penalty for a crime or infraction, within the meaning of Section
33 17556 of the Government Code, or changes the definition of a
34 crime within the meaning of Section 6 of Article XIII B of the
35 California Constitution.